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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,597	03/05/1999	WILLIAM BUTLER COWDEN	120081.403	2400

500 7590 01/02/2003

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/142,597	Applicant(s) Cowden et al.
	Examiner S. Devi, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 30, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-4, 6-8, 15-17 and 19-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4, 6-8, 15-17, and 19-21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 09/10/02 (paper no. 20) in response to the Office Action mailed 04/10/02 (paper no. 18).

Status of Claims

2) Claims 1 and 15 have been amended via the amendment filed 09/10/02.

Claims 1-4, 6-8, 15-17 and 19-21 are pending and are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

5) The rejection of claims 1 and 2 made in paragraph 12 of the Office Action mailed 06/21/00 (paper no. 7) and maintained in paragraph 13 of the Office Action mailed 03/21/01 (paper no. 10) under 35 U.S.C § 103(a) as being unpatentable over Zhang *et al.* (*Acta Virologica* 38: 327-332, 1994), or Gajdosova *et al.* (*Acta Virologica* 38: 339-344, 1994), each in view of Levy *et al.* (*Eur. J. Epidemiol.* 5: 447-453, 1989, abstract), or Roue *et al.* (*Lancet* 341: 1094-1095, 1993), is withdrawn in light of Applicants' amendments to the claims and/or the base claims.

6) The rejection of claims 15, 16, 20 and 21 made in paragraph 12 of the Office Action mailed 06/21/00 (paper no. 7) and maintained in paragraph 13 of the Office Action mailed 03/21/01 (paper no. 10) under 35 U.S.C § 103(a) as being unpatentable over Zhang *et al.* (*Acta Virologica* 38: 327-332, 1994), or Gajdosova *et al.* (*Acta Virologica* 38: 339-344, 1994), each in view of Levy *et al.* (*Eur. J. Epidemiol.* 5: 447-453, 1989, abstract), or Roue *et al.* (*Lancet* 341: 1094-1095, 1993), is withdrawn. Applicants are asked to note the new/modified rejection made below.

7) The rejection of claims 1 and 15 made in paragraph 9(a) of the Office Action mailed 04/10/02 (paper no. 18) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

8) The rejection of claims 2-4, 6-8, 16, 17 and 19-21 made in paragraph 9(b) of the Office Action mailed 04/10/02 (paper no. 18) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s).

9) The rejection of 15-17 and 19-21 made in paragraph 7 of the Office Action mailed 06/21/00 (paper no. 7) and maintained in paragraph 12 of the Office Action filed 03/21/01 (paper no. 10) and paragraph 7 of the Office Action mailed 04/10/02 (paper no. 18) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn.

Rejection(s) Maintained

10) The rejection of 1-4 and 6-8 made in paragraph 7 of the Office Action mailed 06/21/00 (paper no. 7) and maintained in paragraph 12 of the Office Action filed 03/21/01 (paper no. 10) and paragraph 7 of the Office Action mailed 04/10/02 (paper no. 18) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is maintained for reasons set forth therein and herebelow.

It is noted that Applicants have amended claims 1 and 15 by replacing the recitation "preventing, inhibiting, delaying onset of or ameliorating the effects" with --a prophylaxis or treatment--. It is also noted that Applicants have narrowed the scope of the claims to --insulin-dependent diabetes mellitus-- autoimmune disease.

Applicants contend that the specification and the Cowden Declaration show that preparations of non-infectious *C. burnetii* as well as "some but not other components derived therefrom" retain activity and thereby provide a method for preventing, inhibiting, delaying onset of or ameliorating the effects of an autoimmune disease in a mammal by administering to said mammal an autoimmune-preventing effective amount of non-infectious *Coxiella burnetii* or "one or more components therefrom". Yet Applicants submit that a component of *C. burnetii* may be used to practice the full scope of the claimed method. Applicants point to pages 17 and 18 of the specification and state that the specification teaches the effective dosage unit of the active component that may be used. Applicants assert that the Cowden Declaration demonstrates that a

delipidated extract of *C. burnetii* containing one or more active components of *C. burnetii* can be distinguished from inactive *C. burnetii* components by way of DMSO extraction. Applicants state that Examples 1-5 use the well accepted NOD mouse model system for IDDM wherein a non-infectious form of *C. burnetii* is used.

Applicants' arguments have been carefully considered, but are non-persuasive. The instant claims are not directed to a method of making active or inactive antigenic components of *C. burnetii*, but to a method for prophylaxis or treatment of IDDM in a mammal comprising administering "one or more antigenic components" from *C. burnetii*. The broadly recited "one or more antigenic components" from *C. burnetii* are required to necessarily have a prophylactic or therapeutic effect against IDDM. As set forth in paragraph 7 of the Office Action mailed 04/10/02 (paper no. 18), the claimed method is enabled when the CMR residue and the DMSO extract of *C. burnetii* are used as therapeutic components in a mammal having IDDM. However, the other antigenic components, such as, a CME component and the LPS antigenic components of *C. burnetii* have been demonstrated **not** to exert a therapeutic or prophylactic effect against IDDM. Other antigenic components of *C. burnetii* such as "membrane/wall preparation" and an "endospore preparation" of a *Coxiella* species (let alone of *C. burnetii)* are merely mentioned on page 6 of the specification and have not been demonstrated to be of therapeutic or prophylactic significance in mammals with IDDM. The predictability or unpredictability factor is one of the *Wands* factors to be considered while determining the issue of undue experimentation. Although one of skill in the art may be able to produce several antigenic components of *C. burnetii*, one cannot predict that any "one or more antigenic components of *C. burnetii*" other than the CMR residue and the DMSO extract would be prophylactic or therapeutic against IDDM and are usable in the claimed method. The disclosure within the instant specification as well as the data provided in the Cowden Declaration clearly establish that one of skill in the art cannot extrapolate the IDDM-delaying effect of one antigenic component of *C. burnetii,* such as the CMR residue or the DMSO extract, to another antigenic component of *C. burnetii,* such as the CME component or the LPS fraction. A myriad of inoperative antigenic components of non-infectious *Coxiella burnetii,* some with the demonstrated non-therapeutic or non-prophylactic effect against IDDM, are currently encompassed in the scope of the method claims which fail to meet the scope of

enablement requirement of 35 U.S.C. 112, first paragraph. The rejection stands.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

11) Claims 1-4 and 6-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is confusing in the recitation: "treatment .....autoimmune-preventing effective amount", because it is unclear how an autoimmune-preventing amount can be effective in a 'treatment' as opposed to prevention. Treatment does not necessarily involve prevention. It is suggested that Applicants delete the recitation "autoimmune-preventing" from the claim.

(b) Claim 1 as amended and claim 3 appear to be redundant or duplicative in scope.

(c) Claims 1 and 15 are incorrect in the recitation "a prophylaxis or treatment". It is suggested that Applicants delete the recitation "a" from the claim.

(d) Claims 2-4, 6-8, 16, 17 and 19-21, which depend directly or indirectly from claims 1 and 15, are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, because of the indefiniteness or vagueness identified above in the base claims.

Rejection(s) under 35 U.S.C. § 102

12) Claims 15-17 and 19-21 are rejected under 35 U.S.C § 102(b) as being anticipated by Zhang *et al.* (*Acta Virologica* 38: 327-332, 1994, already of record), or Gajdosova *et al.* (*Acta Virologica* 38: 339-344, 1994, already of record) or Vodkin *et al.* (*J. Bacteriol.* 170: 1227-1234, 1988, already of record), or Williams *et al.* (*Infect. Immun.* 51: 851-858, 1986, already of record).

It is noted that the recitation "for use in .....a mammal" in claim 15 represents the intended use of the claimed product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey, 152 USPQ 235 (CCPA 1967)* and *In re Otto, 136 USPQ 458, 459 (CCPA 1963)*. The

recitation "for use in .....a mammal" in claim 15 is not given any patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976)* and *Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)*.

Zhang *et al.* teach a composition comprising a purified outer membrane protein of *Coxiella burnetii* (i.e., an antigenic component) and its potential use as a subunit vaccine. The protein is contained in an adjuvant or a pharmaceutically acceptable carrier and is administered to mice and guinea pigs (i.e., laboratory mammalian test animals). Zhang *et al.* also teach the use of a suspension of killed phase I whole cell vaccines of *Coxiella burnetii* (i.e., QFA) in humans and animals (see page 327, left column).

Gajdosova *et al.* teach a composition comprising phase I *Coxiella burnetii* whole cells or Cb I (i.e., QFA) and/or outer membrane components of *Coxiella burnetii* contained in a pharmaceutically acceptable carrier. A method of administering the compositions to mice, i.e., laboratory mammalian test animals is taught (see abstract; 'Materials and Methods' and 'Discussion'). Mice were immunized with Cb I and an ONPC, i.e., a phase I trichloracetic extract (i.e., an antigenic component of *C. burnetii*) (see abstract and page 343, left column, second full paragraph).

Williams *et al.* disclose a vaccine comprising phase I *Coxiella burnetii* chloroform-methanol residue (CMRV) which induces active immunity against Q fever in mice. Williams *et al.* also teach a whole cell vaccine (WCV), CMR and CMV antigens contained in saline (see abstract; Materials and Methods and Results).

Vodkin *et al.* teach an immunogenic heat shock protein (HSP) antigen (i.e., the antigenic component) of *Coxiella burnetii* and its potential as an efficacious vaccine (see abstract, and the third full paragraph in the left column on page 1230). The protein is immunogenic in mice, elicits antibodies and is suggested as a subunit vaccine (see the last paragraph under 'Discussion'). Vodkin *et al.* also disclose a whole cell lysate (i.e., QFA) of *C. burnetii* that contains the homologous antigenic component (see page 1230, second full paragraph, and Figure 7). The fact

that the antigens were used to immunize mice suggests that the antigens were present in a pharmaceutically acceptable carrier.

Claims 15-17 and 19-21 are anticipated by the prior art of record.

Remarks

13) Claims 1-4, 6-8, 15-17 and 19-21 stand rejected.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December, 2002

S. DEVI, PH.D.
PRIMARY EXAMINER